

# United States Patent and Trademark Office



APPLICATION NO. FILING DATE		ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/056,588 01/23/2002		01/23/2002	Jennifer L. Pavlovic	19369/116/101	4695	
9561	7590	01/30/2004		EXAMINER		
	•	S & O'CONNELL,	PANTUCK, BRADFORD C			
650 THIRD SUITE 600	AVENUE	E SOUTH	ART UNIT	PAPER NUMBER		
MINNEAPO	DLIS, MN	N 55402	3731	10 (		
				DATE MAILED: 01/30/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application	No.	Applicant(s)				
	_	10/056,588		PAVLOVIC, JENNIFER L.				
	Office Action Summary	Examiner		Art Unit				
		Bradford C P		3731				
Period fo	The MAILING DATE of this commo r Reply	inication appears' on the co	over sheet with the c	orrespondence add	dress			
THE I - Exter after - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD MAILING DATE OF THIS COMMU asions of time may be available under the provisions (SIX (6) MONTHS from the mailing date of this coperiod for reply specified above is less than thirty period for reply is specified above, the maximum re to reply within the set or extended period for reply received by the Office later than three month dipatent term adjustment. See 37 CFR 1.704(b).	NICATION.  ns of 37 CFR 1.136(a). In no event, nmunication.  (30) days, a reply within the statutor statutory period will apply and will ex bly will, by statute, cause the applical s after the mailing date of this comm	however, may a reply be tim y minimum of thirty (30) days kpire SIX (6) MONTHS from the top to become ABANDONEE	nely filed s will be considered timely the mailing date of this co D (35 U.S.C. § 133).	mmunication.			
1)⊠	Responsive to communication(s) f	iled on <i>January 14, 2004</i> .						
2a) <u></u>	This action is FINAL.	2b)⊠ This action is non-	final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims							
5)□ 6)⊠ 7)□	Claim(s) 1-31 is/are pending in the application.  4a) Of the above claim(s) 4, 14, 16, and 24-26 is/are withdrawn from consideration.  Claim(s) is/are allowed.  Claim(s) 1-3,5-13,15,17-23 and 27-31 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or election requirement.							
Applicati	on Papers							
9)[	The specification is objected to by	the Examiner.			·			
10)⊠	The drawing(s) filed on <u>17 May 20</u>	<u>02</u> is/are: a)□ accepted o	or b)⊠ objected to t	by the Examiner.				
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
	Replacement drawing sheet(s) includi	=						
	The oath or declaration is objected	to by the Examiner. Note	the attached Office	Action or form P1	O-152.			
	ınder 35 U.S.C. §§ 119 and 120							
* 5 13)	Acknowledgment is made of a cla All b) Some * c) None of 1. Certified copies of the priori 2. Certified copies of the priori 3. Copies of the certified copie application from the Interna See the attached detailed Office ac acknowledgment is made of a claim ince a specific reference was included. 7 CFR 1.78. ) The translation of the foreign acknowledgment is made of a claim	ty documents have been in the documents have been in the documents have been in the soft the priority document tional Bureau (PCT Rule of tion for a list of the certifier in for domestic priority under the direction of the priority under anguage provisional appliant for domestic priority under	received. received in Applications have been received in Application in Applicati	on No ed in this National sed. e) (to a provisional in an Application leived. and/or 121 since set	application) Data Sheet. a specific			
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2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review mation Disclosure Statement(s) (PTO-1449	(PTO-948) 5	) Interview Summary ) Notice of Informal P ) Other:					

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#### **DETAILED ACTION**

### Election/Restrictions

1. Applicant's election without traverse of Claims 1-3, 5-13, 15, 17-23, and 27-31 in Paper No. 11 is acknowledged.

### **Drawings**

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show [label] component 70, as described in the specification. Figure 5d should have number 70 labeled. Figures 8 and 9 should have fiber matrix 14 labeled [see specification page 24, 2<sup>nd</sup> and 3<sup>rd</sup> full paragraphs]. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 3. Claims 1, 5, 6, 8, 9, 13, 15, 19, 20, 27, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,610,077 to Hancock et al. Regarding Claims 1, 19, and 20 Hancock discloses an emboli filter (70), for catching debris in a blood vessel. With reference to *Figure 4A*, Hancock discloses two flexible wires (72 and 74) oriented to define a perimeter. These wires are quite thin and can therefore be flexed with minimal force applied. These wires form a *frame*. Hancock also discloses a fiber matrix (76) [Column 7, lines 52-54] secured to the frame. The fibers are spun (wrapped) around the two wires (72 and 74) criss-cross to form many spaces, interstices and pores between them. The filter (70) is carried on a guide wire (28) [Column 7, lines 44-47]. The filter is collapsible and expandable to engage the walls of the lumen [Column 8, lines 1-13].
- 4. Regarding Claims 5, 6, 8, and 9, Hancock discloses a self-expanding filter. The loops of wire (72 and 74) self-expand because they are made out of nitinol [Column 8, lines 5-11].
- Regarding Claims 15 and 27, the fibers (76) are randomly bent and twisted, as they are strewn from wire (72) to wire (74) [embodiment shown in Figure 4A].

  Therefore, the pores between the fibers (76) will also be randomly, or irregularly, shaped.
- 6. Regarding Claim 13, Hancock discloses a single strand, which forms the fiber of the matrix [Column 7, lines 52-54].

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7. Regarding Claim 30, Hancock's wire (24) is said to have a diameter of 0.003 inches, and is the same component as wire (70) [Column 7, lines 3-7; compare Figure 1B with Figure 4A].

8. Claims 1-3, 5-7, 10-12, 17-23, 28, 29, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,540,768 to Diaz et al. Regarding Claims 1, 19, and 20, Diaz discloses an emboli trap with a wire frame. The wire frame has a plurality of wires (S), which define a circular perimeter [Fig. 24]. Each segment (S) can be considered a separated wire segment. Wires (50/51) in Figure 3 also define a circular perimeter. Any cut taken from conical filter shown in Figures 3-5b will be a circle, and wire (50) will intersect that circle.

Diaz discloses a fiber matrix ("filter membrane 20") secured to the wire frame [Column 5, lines 22-28]. Diaz's fiber matrix allows blood to pass, but not particulate matter [Column 5, lines 22-28]. Figure 5A shows the filter in its collapsed configuration, and Figure 5B shows it in its expanded configuration. Diaz's filter is carried by a guide wire (10) [Column 5, lines 3-10].

Regarding the method of manufacture of the filter ["plurality of wires on which said fibers are spun to form a matrix"], Diaz's filter is capable of being manufactured in this way.

9. Regarding Claims 2 and 3, Diaz's filter is collapsible and does not need a catheter/constraining wall in order to collapse—it has its own mechanism for

collapsing as seen in the progression from Figure 2 to Figure 1 and described in Column 5, lines 3-10.

- 10. Regarding Claims 5, 6, and 29, Diaz's wire frame (50/51) is metallic [Column 5, lines 19-21]. They can also be made of nitinol [Column 5, lines 43-47]. Wires (S) are also assumed to be metallic, because all of the other structural support elements (50/51) are disclosed as being made out of stainless steel or nitinol.
- 11. Regarding Claims 7 and 23, Diaz's fiber matrix (20) and integral wire frame (50/51) form boundaries defining many pores. The mesh is connected to the wire frame (50/51) and being that the mesh has many pores, some of these pores will abut the frame, forming pores together with the wire.
- 12. Regarding Claims 10, 11, 12, and 31, Diaz's fibers (20) are capable of being formed by electrospinning. The fibers (20) are also capable of being applied individually. They are also capable of being applied in a flowable state, as they are made out of a metal [Column 5, lines 36-40], and have a liquid form when heated. However, no additional structure is claimed by claiming a method of manufacturing the fibers, or a method of applying them to the frame (50/51).
- Regarding Claim 17, Diaz discloses pores, which are 50-150 microns in size [Column 5, lines 27-30].
- 14. Regarding Claim 18, Diaz discloses a filter material having laser-drilled holes with an open area of 10-50 percent. This open area corresponds to a hole size of 50-300 microns [Column 8, lines 36-51]. Therefore his mesh, which also has a hole size

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of 50-300 microns [Column 5, lines 27-30] will also have an open area of between 10-50 percent.

- 15. Regarding Claims 21 and 22, Diaz discloses a flexible catheter [sheath] (180) that holds the frame in its collapsed position [see Fig. 14; Column 7, lines 61-65]. Nylon is a flexible material, and the catheter must navigate through the turns in the blood vessel. The catheter (180) is carried by guide wire (164) and holds the flexible frame of the emboli trap inside of it [see Fig. 15].
- 16. Regarding Claim 28, Diaz's frame is windsock shaped [Figures 5B, 7, 9, 11, 14].

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- U.S. Patent No. 6,558,405 B1 to McInnes
- U.S. Patent No. 6,458,502 B2 to Don Michael et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BĊP

January 23, 2004

MICHAEL J. MILANO

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 3700